

COMMISSION DELEGATED REGULATION (EU) No/.....

of

on a common safety method for assessing conformity with the requirements for obtaining a railway single safety certificate and repealing Regulation (EU) 1158/2010 and Annex I and Annex II of Regulation (EC) 653/2007

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)¹, and in particular Article 6(1) thereof,

Whereas:

- (1) One of the purposes of Directive (EU) 2016/798 is to improve access to the market for rail transport services by defining common principles for the management, regulation and supervision of railway safety. Directive (EU) 2016/798 also provides equal treatment for all railway undertakings by applying the single safety certification requirements throughout the European Union.
- (2) Article 6(1)(b) of Directive (EU) 2016/798 provides a framework for authorities issuing single safety certificates and safety authorisations to harmonise their decision-making process and criteria across the European Union, through the application of common safety methods (CSMs). This Regulation sets out a CSM for assessing conformity with the requirements for obtaining a railway single safety certificate.
- (3) The CSMs have been gradually introduced to describe how the safety levels, the achievement of safety targets and compliance with other safety requirements are assessed.
- (4) The CSMs are to be revised at regular intervals, taking into account the experience gained from their application and the global development of railway safety and with the objective of generally maintaining and, where reasonably practicable, continuously improving safety, in accordance with Article 6(5) of Directive (EU) 2016/798.
- (5) On 1 September 2016 the Commission issued a mandate to the European Union Agency for Railways (the ‘Agency’) in accordance with Directive (EU) 2016/798 to revise the common safety method for assessing conformity with the requirements for obtaining railway safety certificates referred to in Commission Regulation (EU) No 1158/2010 of 9 December 2010², the common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation referred to in Commission Regulation (EU) No 1169/2010 of 10 December 2010³ and the common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation referred to in Commission Regulation (EU) No

¹ OJ L 138, 26.05.2016, p. 102.

² OJ L 326, 10.12.2010, p. 11.

³ OJ L 327, 11.12.2010, p.13.

1077/2012 of 16 November 2012⁴. This mandate to the Agency is aimed at further harmonising conformity assessment approaches among Member States. The Agency submitted its recommendation on the revision of the CSMS to the Commission, supported by an impact assessment report to address the mandate of the Commission. This Regulation is based on that Agency recommendation.

- (6) In accordance with Article 10 of Directive (EU) 2016/798, the single safety certificates issued by the Agency or by the national safety authorities (NSAs) as appropriate, give evidence that the railway undertakings have established their safety management system as provided for in Article 9 of Directive (EU) 2016/798 and are capable of complying with the relevant requirements thereof.
- (7) The purpose of the safety management system is to ensure that the railway undertakings and infrastructure managers achieve their business objectives in a safe manner. The safety management system is often integrated with other management systems to increase the overall performance of the organisation and reduce costs while mutualising the efforts at all levels of the organisation. To this end, the common framework of the ISO High Level Structure⁵ is used to functionally cluster the requirements of the safety management system, as referred to in Article 9 of Directive (EU) 2016/798. This framework also facilitates the understanding and application of a process approach by the railway undertakings and infrastructure managers when developing, implementing, maintaining and continually improving their safety management system.
- (8) Once issued with a single safety certificate the applicant should continue to use its safety management system as referred to in Article 9 of Directive (EU) 2016/798.
- (9) The human plays a central role in the safe and efficient operation of the railway. Therefore, it is essential that the railway undertakings and infrastructure managers take a systematic approach to supporting human performance and managing human factors within the safety management system.
- (10) The way safety is perceived, valued and prioritised in an organisation reflects the real commitment to safety at all levels in the organisation. Therefore, it is also important for railway undertakings and infrastructure managers to identify the actions and behaviours that can positively shape a safety culture through their safety management system.
- (11) Commission Regulation (EC) No 653/2007 of 13 June 2007 on the use of a common European format for safety certificates and application documents in accordance with Article 10 of Directive 2004/49/EC of the European Parliament and of the Council and on the validity of safety certificates delivered under Directive 2001/14/EC⁶ provides standard format for safety certificates. Annex I to Regulation (EC) No 653/2007 is replaced by Annex VI of Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007⁷. Article 10 of Directive (EU) 2016/798 sets out a new safety certification regime for the issuing of single safety certificates. In addition, certificates issued to entities in charge of maintenance in accordance with Regulation (EU) No 445/2011 and single safety certificates issued to railway undertakings being also entities in charge of maintenance for their own vehicles should be managed independently in order to avoid additional burdens and costs resulting from

⁴ OJ L 320, 17.11.2012, p. 3.

⁵ ISO/IEC Directives, Part 1, consolidated supplement 2016, Annex SL Appendix 2.

⁶ OJ L 153, 14.6.2007, p.9.

⁷ OJ L 122, 11.5.2011, p.22.

their renewal, update or revocation. Annex I and Annex II of Regulation (EC) No 653/2007 should therefore be repealed by this Regulation. A new format of single safety certificate is included in this Regulation.

- (12) Article 10 of Directive (EU) 2016/798 assigns the role and responsibilities for the safety certification either to the Agency in accordance with Article 10(5) of Directive (EU) 2016/798 or to an NSA in accordance with Article 10(8) of Directive (EU) 2016/798. In order to facilitate a consistent understanding amongst these bodies on how to implement a competence management system and to reinforce the mutual trust between them, a minimum set of uniform competency requirements for staff undertaking conformity assessment activities and a sequence of activities to implement a competence management system are set out in this Regulation.
- (13) The safety management system should take into account the fact that Council Directive 89/391/EC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work⁸ and its relevant individual directives are fully applicable to the protection of the health and safety of workers engaged in railway transport. It does not create any additional responsibilities or tasks for the safety certification body other than to check if health and safety risks have been taken into account by the applicant for a single safety certificate. Responsibility for checking the compliance with Council Directive 89/391/EC may still be allocated on other competent authorities appointed by the Member State.
- (14) The safety management system should where relevant take into consideration the potential additional risks generated by carrying dangerous goods containments and thereby, should also take account of Council Directive 2008/68/EC of 24 September 2008 on the inland transport of dangerous goods⁹.
- (15) Without prejudice to the responsibilities set out in Article 4(3) of Directive (EU) 2016/798 for the safe operation of trains, railway undertakings may play different roles within the Union rail system such as providing specific products or services (e.g. the provision of maintenance services in accordance with Article 14 of Directive (EU) 2016/798). Alternatively, these products or services may also be partly or wholly provided by contractors, partners or suppliers.
- (16) In assessing conformity with safety requirements of products or services provided by railway undertakings or their contractors, partners or suppliers, authorisations, recognitions or certificates granted in accordance with relevant Union law to railway undertakings or their contractors, partners or suppliers should be considered as valid evidence of compliance with the relevant assessment criteria (or parts of them) defined in this Regulation.
- (17) In the cases provided for in Article 14(4) of Directive (EU) 2016/798, the certification of entities in charge of maintenance and of maintenance workshops as appropriate provide sufficient evidence that railway undertakings are capable, through their safety management system, to control the risks related to the maintenance of vehicles, including the use of contractors.
- (18) Training centres should be recognised by the competent authority for providing training courses for train drivers and train candidate drivers in accordance with Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in

⁸ OJ L 183, 26.06.1989, p.1.

⁹ OJ L 260, 30.09.2008, p.13.

the Community¹⁰. Training centres play an important role to ensure that train drivers are competent for the safety-related tasks assigned to them. In that respect, training centres should be competent in regard to the training they carry out and their recognition by a competent authority should where relevant be taken into account by the safety certification body when carrying out an assessment of the competence management system.

- (19) Commission Regulation (EU) No 1158/2010 has become obsolete and should therefore be replaced by this Regulation.

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes a CSM for assessing conformity with requirements for obtaining single safety certificates as referred to in Article 6(1)(b) of Directive (EU) 2016/798.

Article 2

Scope

1. Safety certification bodies shall use this Regulation in order to assess compliance with the legal obligation in Article 10(3) of Directive (EU) 2016/798 on a railway undertaking to provide an application file containing documentary evidence that it has established its safety management system in accordance with Article 9 of Directive (EU) 2016/798 and, in collaboration with relevant NSA(s) as appropriate, that it meets the requirements laid down in the relevant national rules notified in accordance with Article 8 of Directive (EU) 2016/798.
2. Pursuant to Article 9(1) of Directive (EU) 2016/798, the applicant for a single safety certificate shall demonstrate compliance with the assessment criteria set out in Annex II in order to provide the documentary evidence referred to in paragraph 1.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (a) ‘safety certification body’ means the body responsible for the issuing of single safety certificates, either the Agency in accordance with Article 10(5) of Directive (EU) 2016/798 or an NSA in accordance with Article 10(8) of Directive (EU) 2016/798;
- (b) ‘human factors’ means all of the people or human performance issues that must be considered to assure the lifelong safety and effectiveness of a system or organisation;
- (c) ‘safety culture’ means the combination of values, beliefs, vision, purpose, policies, objectives and leadership styles that impact on an organisation’s safety. A positive safety culture is characterised by awareness, assessment and action on safety matters in all these areas, and is supported by an open communications style throughout the whole organisation;

¹⁰ OJ L 315, 3.12.2007, p. 51

- (d) 'human-centred approach' means a philosophy for considering the needs, capabilities and behaviours of people first and then designing to accommodate those needs, capabilities and behaviours;
- (e) 'dangerous goods' means those substances and articles the carriage of which is prohibited by RID, or authorised only under the conditions prescribed therein;
- (f) 'RID' means the Regulations concerning the International Carriage of Dangerous Goods by Rail, as adopted under Directive 2008/68/EC;
- (g) 'residual concern' means a minor issue identified during the assessment of an application for a single safety certificate which does not prevent the issue of it and can be used to inform later supervision.

Article 4

Safety assessment process

1. The safety certification body in collaboration with relevant NSA(s) as appropriate shall apply the process set out in Annex I to this Regulation and the assessment criteria set out in Annex II to this Regulation for assessing new, update or renewal applications for single safety certificates in accordance with Article 10 of Directive (EU) 2016/798.
2. The safety certification body and relevant NSA(s) as appropriate shall coordinate with the applicant, upon its request, before the submission of its application for a single safety certificate in order to help it understand what is expected of it and what it should expect from the safety certification body and relevant NSA(s) as appropriate.
3. Products or services provided by contractors, partners or suppliers to railway undertakings shall be accepted as proof of the ability of the railway undertakings to conform to the relevant assessment criteria specified in Annex II if such products or services are authorised, recognised or certified in accordance with relevant Union law.

Article 5

Assessment of compliance with relevant notified national rules

1. The assessment of the elements referred to in Article 10(3)(b) of Directive (EU) 2016/798 shall cover for the intended area of operation those notified national rules that relate to operational requirements not yet mandated in the Technical Specification for Interoperability relating to the operation and traffic management subsystem or in any other applicable European legislation.
2. In cases where railway undertakings travel to stations in neighbouring Member States with similar network characteristics and similar operating rules, when those stations are close to the border, as referred to in Article 10(8) of Directive (EU) 2016/798, the relevant NSAs shall cooperate to ensure that the relevant national rules, as referred to in paragraph 1, notified in their respective Member State, are met before the issuing of the single safety certificate.

Article 6

Interface with supervision

1. The safety certification body shall exchange information gathered during the assessment of the application for a single safety certificate with the relevant NSA(s) for the purposes of supervision for the duration of that single safety certificate in accordance with Article 17(11) of Directive (EU) 2016/798.

2. The information referred to in paragraph 1 shall include a description of any residual concern and agreed action to be followed up during supervision activities.

Article 7

Competence of the persons involved in conformity assessment activities

1. The safety certification body responsible for conformity assessment shall have a competence management system in place to ensure that the conformity assessment activities are undertaken by competent persons, which shall include:

- (a) The development of competence profiles for each job, position or role;
- (b) The selection and/or recruitment of staff, assessing them against the established competence levels;
- (c) The maintenance of competence by training, development and assessment of staff against the established competence levels.

2. The competence management system shall ensure through its processes (e.g. training, mentoring, shadowing, on-the-job training) that staff involved in conformity assessment demonstrate the appropriate level of competence for the performance of their tasks. The competencies listed below must be held by the individual carrying out the conformity assessment or, in the case of team work, must be shared amongst the team members:

- (a) Knowledge of the relevant regulatory framework as it applies to conformity assessment;
- (b) Knowledge of the functioning of the railway system;
- (c) Appropriate level of critical analysis to enable them to carry out assessment tasks;
- (d) Experience of the assessment of a safety or similar management system in the railway sector or a safety management system in a sector with equivalent operational and technical challenges;
- (e) Relevant non-technical competencies, including, but not limited to, problem solving, communication and team working that enable them to carry out their tasks.

3. In cases where during the conformity assessment, the safety certification body or the relevant NSA(s) as appropriate undertakes on-site visits, inspections and audits of the railway undertakings, as referred to in Article 10(5) of Directive (EU) 2016/798, competencies set out in Article 7 of Commission Delegated Regulation (EU) No/.. of .. on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation¹¹ shall apply equally to staff carrying out the on-site visits, inspections and audits.

Article 8

Repeal

Commission Regulation (EU) No 1158/2010, Annex I and Annex II of Regulation (EC) No 653/2007 are repealed with effect from 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798. They shall be repealed with effect from 16 June 2020 in all Member States.

References to the Regulations which are repealed entirely or in parts shall be construed as references to this Regulation.

¹¹ OJ: Please insert the number of the revised CSM Regulation on supervision.

Article 9

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798. It shall apply from 16 June 2020 in all Member States.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at

For the Commission

The President

DRAFT

**PROCESS FOR ASSESSING CONFORMITY WITH REQUIREMENTS FOR
OBTAINING SAFETY CERTIFICATES TO BE ISSUED IN ACCORDANCE WITH
ARTICLE 10 OF DIRECTIVE (EU) 2016/798**

1. General

1.1. The safety certification body and as appropriate relevant NSA(s) shall develop a structured and auditable process for the complete activity which takes into account the elements below. This ensures that the process for assessing conformity with the requirements for obtaining a single safety certificate is iterative, as shown in the diagram below (see Figure 1 in the Appendix), where the safety certification body and as appropriate relevant NSA(s) may make reasonable requests for further information or re-submission in accordance with this Regulation.

2. Receipt of application

2.1. After receiving the application for a single safety certificate, the safety certification body shall formally and promptly acknowledge receipt of the application.

2.2. The safety certification body and as appropriate relevant NSA(s) shall assign competent resources to deliver the assessment process.

3. Initial screen

3.1. In accordance with the one month timescale, as referred to in Article 10(6) or where applicable in Article 10(8) of Directive (EU) 2016/798, for making an initial response to the applicant, the safety certification body in coordination with relevant NSA(s) as appropriate shall undertake promptly on receipt of the application an initial screen to check that:

- (a) the applicant has provided the basic information which is either required by the legislation or needed for it to be processed effectively;
- (b) the application file contains sufficient evidence and is structured and internally cross-referenced so that it can be properly assessed against the CSM assessment criteria and relevant notified national rules in accordance with Article 5 of this Regulation. The safety certification body in coordination with relevant NSA(s) as appropriate shall conduct an initial review of the actual content of the evidence contained in the application to make an initial judgement on the quality, sufficiency and appropriateness of the safety management system;
- (c) the current status of the action plan (or plans) established by the railway undertaking to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment is included;
- (d) the current status of the action plan (or plans) established by the railway undertaking to resolve residual concerns from previous assessment is included.

3.2. The relevant NSA(s) shall also check that the evidence for the type, extent and intended area of operation is clearly identified.

3.3. Following the checks referred to in paragraph 3.1 and paragraph 3.2, the safety certification body and as appropriate relevant NSA(s) shall decide if there are any areas in which, for their respective part, further information is necessary. Where relevant, the safety certification body and as appropriate relevant NSA(s) shall promptly seek only the information that they deem reasonably necessary to support their assessment.

3.4. The safety certification body and as appropriate relevant NSA(s) shall read a sufficient sample of the application, each for their own part, to check that its content is understandable. If it is clearly not, the safety certification body and as appropriate relevant NSA(s) shall decide, each for their own part, whether it should be returned, with a request for an improved version.

3.5. If the application is fundamentally deficient, such that it clearly could not lead to the issue of a single safety certificate without major revision, irrespective of whether the linguistic quality referred to in paragraph 3.4 is satisfactory or not, the safety certification body and as appropriate relevant NSA(s) shall discuss this without delay with the applicant and if the conclusion is confirmed, the safety certification body shall reject the application, stating the reasons in writing, and request the applicant to make a re-submission.

3.6. Where the application has minor deficiencies, but is otherwise of sufficient quality to allow the main assessment to proceed, the safety certification body in coordination with the relevant NSA(s) as appropriate shall request the necessary further information promptly, including justifications and details of the timescale for the applicant's response. The timeframe for providing supplementary information shall be reasonable, proportionate to the difficulty of providing the information requested and agreed with the applicant as soon as it is informed that its file is not complete. If the applicant does not provide the required information within the given timescale, the safety certification body may decide to extend the timescale for the applicant's response or in the last resort, to reject the application without prior notice.

3.7. Any supplementary information sent as part of the application shall be kept on file and where relevant, shared with whom it may concern within the safety certification body and as appropriate relevant NSA(s).

4. Detailed assessment

4.1. After the completion of the initial screen stage, the safety certification body and as appropriate relevant NSA(s) shall proceed, each for their own part, to the detailed assessment of the application file (see Figure 2 in the Appendix), using the CSM assessment criteria and relevant notified national rules in accordance with Article 5 of this Regulation.

4.2. In undertaking the detailed assessment referred to in paragraph 4.1, in accordance with Article 18(1) of Directive (EU) 2016/798, the safety certification body and as appropriate relevant NSA(s) shall exercise professional judgment, be impartial and proportionate, and provide documented reasons for conclusions reached.

4.3. The safety certification body and as appropriate relevant NSA(s) shall have arrangements in place within their respective organisation to ensure that the assessment is completed in a timely manner and in any case, within a timescale allowing the safety certification body to take its final decision not more than four months following the acknowledgement of the completeness of the application file.

4.4. The assessment shall determine whether the CSM assessment criteria and relevant notified national rules are complied with and in the case of identified instances of non-compliance, whether further information shall be requested. During the assessment, the safety certification body and as appropriate relevant NSA(s) shall also seek evidence that the CSM assessment criteria and relevant notified national rules have been met from the outputs of the safety management system processes, using sampling methods where appropriate, to ensure that the applicant has understood and can meet the requirements according to the type and extent of the railway operations and the intended area of operation.

4.5. Any identified instances of non-compliance that are considered major or unacceptable shall be resolved to the satisfaction of the safety certification body and lead to an update of the application file where appropriate before the single safety certificate can be issued. If it is a

residual concern only, the matter can be deferred for consideration to supervision and/or actions can be agreed upon with the applicant, based on its proposal for updating the application file. In such a case formal resolution of the issue will take place after the issue of the single safety certificate.

4.6. The safety certification body and as appropriate relevant NSA(s) shall be transparent on how they judge the severity of each identified instance of non-compliance.

4.7. When identifying a point of query or a possible instance of non-compliance, the safety certification body and as appropriate relevant NSA(s) shall be specific and help the applicant understand the level of detail expected in the response. To that end, the safety certification body and as appropriate relevant NSA(s) shall:

- (a) refer accurately to the relevant CSM assessment criteria and notified national rules and help the applicant to understand the identified areas of non-compliance;
- (b) identify the relevant part of related regulations, rules and standards;
- (c) state why the individual CSM assessment criterion or notified national rule, including any related legislation, is not met;
- (d) agree with the applicant on further commitments, documents and any other supporting information to be provided, as required by the level of detail of the CSM assessment criterion or the notified national rule; and
- (e) specify and agree with the applicant on a timeframe for compliance, reasonable and proportionate to the difficulty of providing the information requested.

4.8. If the applicant significantly delays providing the requested information, the safety certification body and as appropriate relevant NSA(s) might need to suspend the assessment (or extend the time in which it reaches a decision) or in the last resort, reject the application, which could have implications for the operation either starting at a specified date, or continuing after expiry of the existing single safety certificate, if the application is for a renewal.

4.9. The timeframe for the assessment may only be suspended (or extended), upon decision of the safety certification body in coordination with relevant NSA(s) as appropriate and with the agreement of the applicant in the following cases:

- (a) major deficiencies or multiple minor deficiencies that, considered collectively, may raise the category to a major deficiency of evidence are identified, such that they prevent the assessment or parts of it to continue, or;
- (b) major non-conformities or multiple minor non-conformities that, considered collectively, may raise the category to a major non-conformity with the CSM assessment criteria and/or relevant notified national rules are found, such that if they were not corrected they would prevent the issuing of the single safety certificate.

4.10. To be satisfactory, the applicant's written responses shall be sufficient to allay the concerns expressed and to demonstrate that its proposed arrangements will meet the relevant criteria or notified national rules.

4.11. Where a response is considered unsatisfactory, it shall be explained precisely why, identifying the further information or demonstration required of the applicant to make it satisfactory.

4.12. If for whatever reason, a final resolution of any issue looks like becoming protracted such that the agreed timeframe for compliance may be exceeded, and deferment of concerns to a later supervision plan is not appropriate, the safety certification body shall promptly discuss it together with the applicant and the relevant NSA(s) as appropriate. If concerns emerge that the

application could be refused, or that it will take a longer time to reach a decision than the timeframe allowed for the assessment, the safety certification body may consider possible contingency procedures.

4.13. To aid its assessment, the safety certification body and/or as appropriate relevant NSA(s) may also decide to undertake on-site audits and inspections. If so, the safety certification body and as appropriate relevant NSA(s) shall coordinate the organisation of such on-site audits and inspections in order to plan efficiently their individual or joint initiatives without causing unnecessary inconvenience to the applicant. The assessment may also be suspended if the applicant is not able to promptly arrange an audit or inspection within its organisation.

4.14. When it is concluded that either the application meets all requirements or that further progress is unlikely in securing satisfactory responses to outstanding matters, the safety certification body and relevant NSA(s) as appropriate shall complete their assessment by:

- (a) stating whether all criteria have been complied with or whether there are still matters outstanding;
- (b) identifying any residual concern not fully resolved during the assessment to be scrutinised during later supervision;
- (c) identifying any limitation or condition of use to be included in the single safety certificate;
- (d) reporting on the follow-up of major non-compliances identified during supervision activities, as referred to in Article 6 of Commission Delegated Regulation (EU) No ...¹², where appropriate;
- (e) ensuring that the assessment process has been correctly applied; and
- (f) providing the outcome of the assessment, including summary conclusions and an opinion over the issue of the single safety certificate where appropriate, each for their respective part of the assessment.

4.15. The safety certification body and as appropriate relevant NSA(s) shall record and justify in writing all findings and judgments in order to facilitate both the assurance process and the final decision, as well as to assist with any appeal against the final decision.

5. Decision-making

5.1. Based on the conclusions of the completed assessment, a decision shall be made on whether to issue a single safety certificate or to refuse the application. Where a single safety certificate is to be issued, some residual concerns for consideration in later supervision may be identified. A single safety certificate shall not be issued where any major non-compliance with the CSM assessment criteria is identified and not resolved during the assessment.

5.2. Once the decision has been taken and if the decision is to award the single safety certificate, the safety certification body shall prepare a single safety certificate in the standard format set out in Annex III of this Regulation.

5.3. The safety certification body may decide to restrict the scope of the single safety certificate, by identifying limitations or conditions of use, if it is concluded in coordination with relevant NSA(s) as appropriate that these limitations or conditions of use address any major non-compliance that would prevent the issue of the single safety certificate. The single safety certificate shall be updated on request of the applicant after all residual concerns have been addressed in its application file.

¹² OJ: Please insert the number of the revised CSM Regulation on supervision.

5.4. The applicant shall be informed about the final decision and a single safety certificate shall be issued as appropriate.

5.5. If the decision is for refusal or contains limitations or conditions of use other than those defined in the application, the safety certification body shall inform the applicant, giving the reasons for the decision, and notify it of the procedure to request for a review of or to appeal against its decision.

5.6. The safety certification body (if not the Agency) shall notify the Agency, as the system authority for registers and databases of each individual decision to issue, renew, update or revoke single safety certificates in accordance with Article 10(16) of Directive (EU) 2016/798 and Articles 12 and 37(6) of Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004¹³.

6. Closing assessment

6.1. The safety certification body shall complete the administrative closure by ensuring that all documents and records are reviewed, organised and archived. To continually improve its process, the safety certification body shall identify historic information and lessons learned for use by future assessments.

7. Specific provisions for the renewal of a single safety certificate

7.1. A single safety certificate shall be renewed upon request of the applicant before the expiry of its validity to ensure continuity of certification.

7.2. In the case of a renewal application, the safety certification body and relevant NSA(s) as appropriate shall check details of changes to the evidence submitted in the previous application and consider the results of past supervision activities as referred to in Article 6 of Commission Delegated Regulation (EU) No .../..¹⁴ to prioritise or target the relevant CSM assessment criteria and notified national rules upon which to assess the renewal application.

7.3. The safety certification body and as appropriate relevant NSA(s) shall take a proportionate approach to re-assessment, based on the degree of changes proposed. If significant matters of concern are raised during supervision activities, the safety certification body and as appropriate relevant NSA(s) shall decide whether the whole application file needs to be re-assessed.

8. Specific provisions for the update of a single safety certificate

8.1. A single safety certificate shall be updated whenever there is a substantial change proposed to the type or extent of operation in accordance with Article 10(13) of Directive (EU) 2016/798, or in case of extension of the area of operation in accordance with Article 10(14) of Directive (EU) 2016/798.

8.2. Where it proposes to make a substantial change in accordance with paragraph 8.1, the railway undertaking holding the single safety certificate shall notify the safety certification body without delay.

8.3. Following the notification by the railway undertaking as referred to in paragraph 8.2, the safety certification body shall:

- (a) check that the substantial change(s) relating to any potential application is (are) clearly described; and

¹³ OJ L 138, 26.5.2016, p. 1.

¹⁴ OJ: Please insert the number of the revised CSM Regulation on supervision.

- (b) discuss with the railway undertaking and the relevant NSA(s) as appropriate the need for an update of the single safety certificate.

8.4. The safety certification body in coordination with the relevant NSA(s) as appropriate may need to make further enquiries with the applicant before coming to a conclusion, but if the safety certification body considers the proposed change not to be substantial it shall inform the applicant in writing that an update is not required, keeping a record of the decision for the registered file.

8.5. In the case of an update application, the safety certification body and relevant NSA(s) as appropriate shall:

- (a) check details of changes to the evidence submitted in the previous application whereby the current certificate was issued;
- (b) consider the results of past supervision activities as referred to in Article 6 of Commission Delegated Regulation (EU) No ...¹⁵ (in particular, issues relating to the ability of the applicant to effectively implement and monitor its change management process);
- (c) prioritise or target the relevant CSM assessment criteria and notified national rules in order to assess the update application.

8.6. The safety certification body and as appropriate relevant NSA(s) shall take a proportionate approach to re-assessment, based on the degree of changes proposed. If significant matters of concern are raised during supervision activities, the safety certification body and as appropriate relevant NSA(s) shall decide whether the whole application file needs to be re-assessed.

8.7. An application to the safety certification body to update a single safety certificate shall not lead to the extension of its validity period.

8.8. The safety certification body shall decide at the request of the applicant whether the single safety certificate needs to be updated where the conditions under which the single safety certificate was issued are to be changed without any impact on the type, extent or area of operation.

8.9. If a NSA identifies a serious risk for safety during its supervision and decides to take enforcement actions in accordance with Article 17(6) of Directive (EU) 2016/798, it should (where it is not also the safety certification body) inform the Agency as to whether there are any implications from the enforcement actions that may affect the single safety certificate. This should also include whether there is a case for restricting or revoking the single safety certificate. The safety certification body shall decide whether or not the single safety certificate needs updating with restrictions or is to be revoked.

¹⁵ OJ: Please insert the number of the revised CSM Regulation on supervision.

Safety assessment process

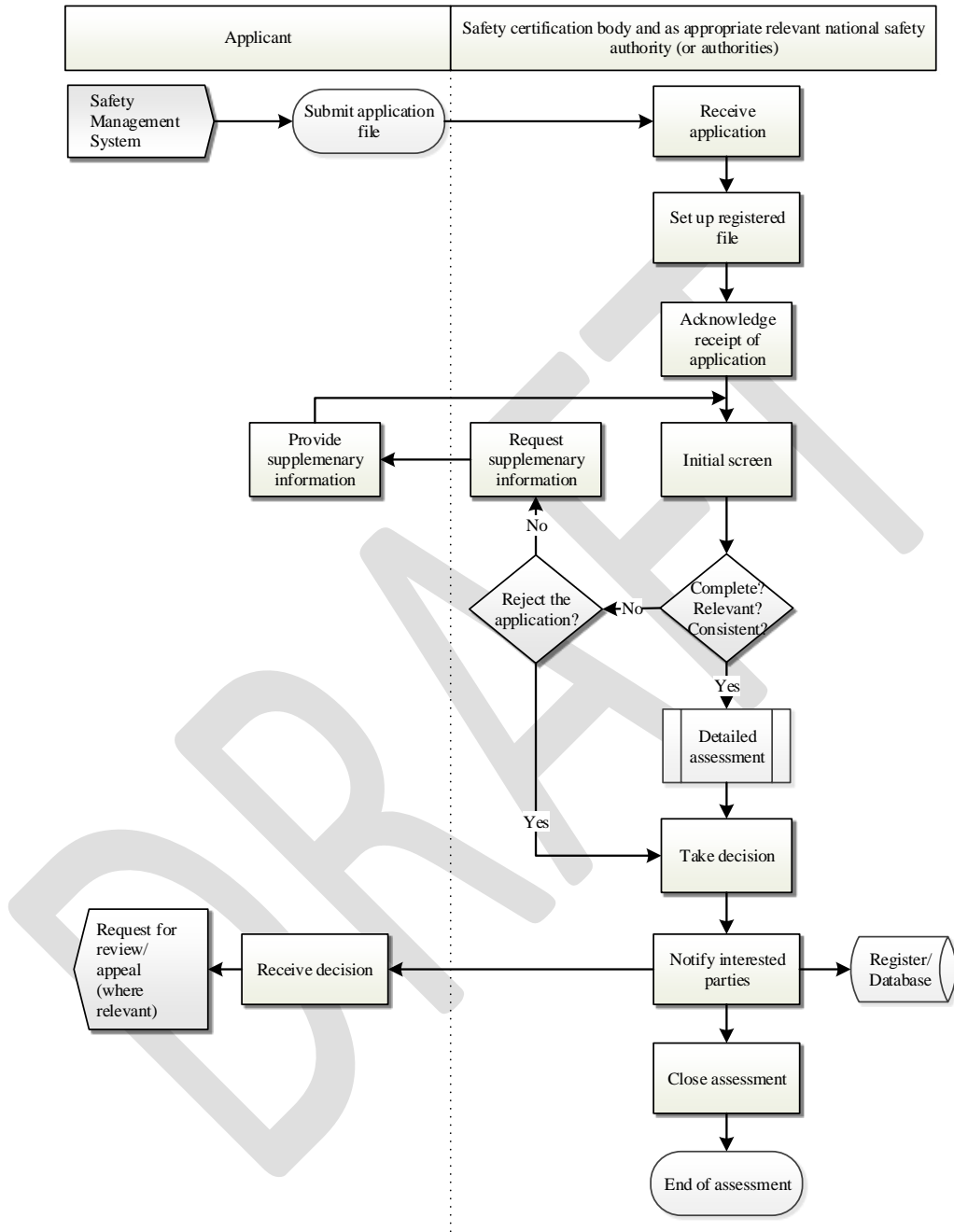


Figure 1: Safety assessment process.

Detailed assessment process

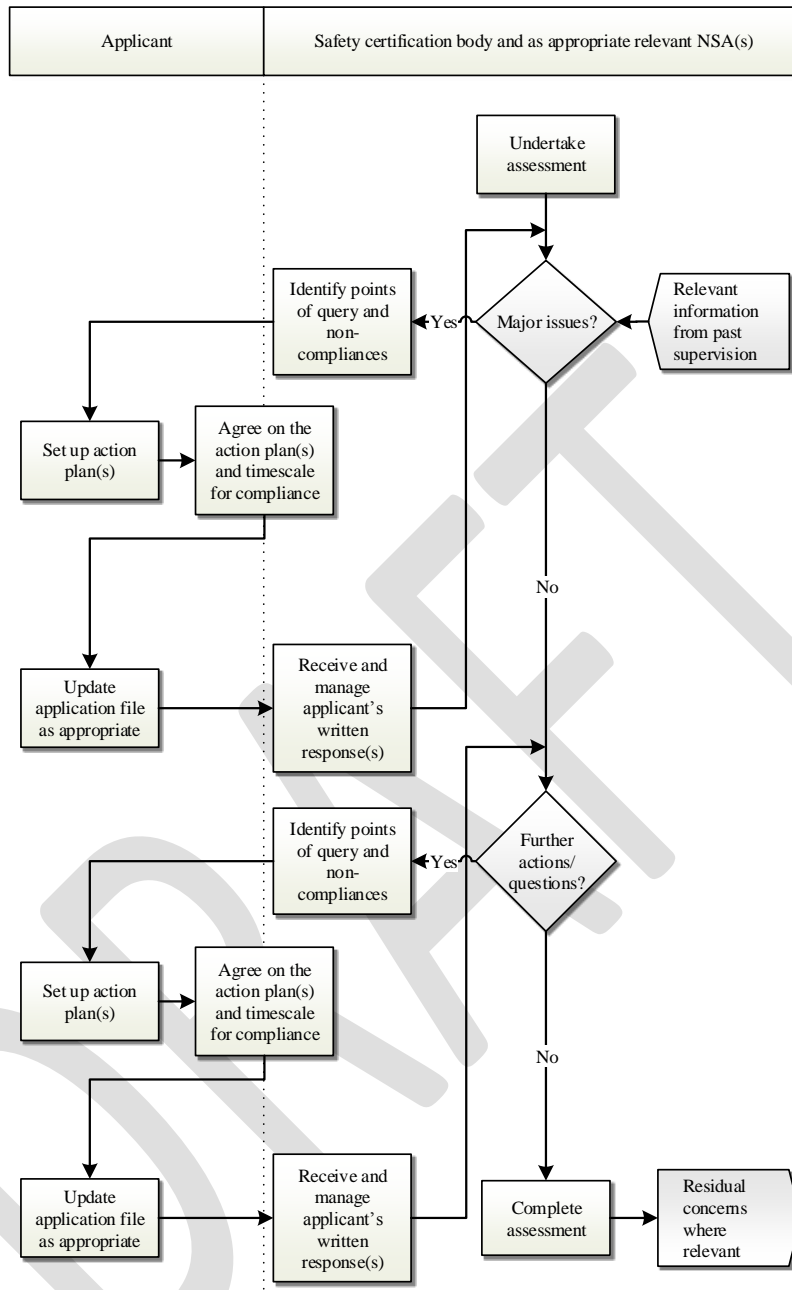


Figure 2: Detailed assessment process.

ANNEX II

CRITERIA FOR ASSESSING CONFORMITY WITH THE REQUIREMENTS FOR OBTAINING SAFETY CERTIFICATES TO BE ISSUED IN ACCORDANCE WITH ARTICLE 10 OF DIRECTIVE (EU) 2016/798 RELATED TO THE RAILWAY UNDERTAKING'S SAFETY MANAGEMENT SYSTEM AS DESCRIBED IN ARTICLE 9 OF THAT DIRECTIVE.

1. CONTEXT OF THE ORGANISATION

1.1. Organisation, context and scope of the safety management system

1.1.1. The organisation shall:

- (a) describe the type, extent and area of its operations;
- (b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors under its control;
- (c) identify interested parties (e.g. regulatory bodies, authorities, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;
- (d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);
- (e) ensure that the requirements referred to in point (d) are taken into account in developing, implementing and maintaining the safety management system;
- (f) describe the scope of the safety management system, indicating which part of the business is included or not in its scope and taking into account the requirements referred to in point (d).

1.2. Human factors

- ###### 1.2.1. The organisation shall demonstrate a systematic approach to integrating and managing human factors within the safety management system. This shall include the use of recognised methods from the field of human factors to address risks associated with the design and use of equipment, tasks and working conditions, taking into account human capabilities as well as limitations, and the influences on human performance.

2. LEADERSHIP

2.1. Leadership and commitment

- ###### 2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:

- (a) taking overall accountability and responsibility for safety;
- (b) ensuring commitment to safety by management at different levels within the organisation through their activities and in their relationships with staff and contractors;
- (c) ensuring that the safety policy and safety objectives are established, understood and are compatible with the strategic direction of the organisation;
- (d) ensuring the integration of the safety management system requirements into the organisation's business processes;

- (e) ensuring that the resources needed for the safety management system are available;
- (f) ensuring that the safety management system is effective in controlling the safety risks posed by the organisation;
- (g) encouraging staff to support compliance with the safety management system requirements;
- (h) promoting continual improvement of the safety management system;
- (i) providing a strategy to ensure that human factors knowledge, methods and a human-centred approach are consistently applied;
- (j) ensuring that safety is considered when identifying and managing the organisation's business risks and explaining how conflict between safety and other goals will be recognised and resolved;
- (k) promoting a positive safety culture in which staff (e.g. front line operators) are not punished for actions, omissions or decisions taken by them that are commensurate with their experience and training, but where gross negligence, wilful violations and destructive acts are not tolerated.

2.2. Safety policy

2.2.1. A document describing the organisation's safety policy is established by the top management and is:

- (a) appropriate to the organisation's type and extent of railway operations;
- (b) approved by the organisation's chief executive (or a representative(s) of the top-management);
- (c) communicated and made available to all staff.

2.2.2. The safety policy shall:

- (a) include a commitment to conform with all legal and other requirements related to safety;
- (b) include a commitment to establish and evaluate the organisation's safety performance against identified safety objectives;
- (c) include a commitment to continual improvement of the safety management system;
- (d) be maintained in accordance with the business strategy and the evaluation of the safety performance of the organisation.

2.3. Organisational roles, responsibilities, accountabilities and authorities

2.3.1. The responsibilities, accountabilities and authorities of staff having a role that affects safety (including management and other staff involved in safety-related tasks) shall be defined, documented, assigned and communicated at all levels within the organisation.

2.3.2. The organisation shall ensure that staff with delegated responsibilities for safety-related tasks shall have the authority, competence and appropriate resources to perform their tasks without being adversely affected by the activities of other business functions.

2.3.3. Delegation of responsibility for safety-related tasks shall be documented and communicated to the relevant staff, accepted and understood.

2.3.4. The organisation shall describe the allocation of roles referred to in paragraph 2.3.1. to business functions within and where relevant, outside the organisation (see 5.3. Contractors, partners and suppliers).

2.4. Consultation of staff and other parties

- 2.4.1. Staff, their representatives and external interested parties, as appropriate and where relevant, shall be consulted in developing, maintaining and improving the safety management system in the relevant parts they are responsible for, including the safety aspects of operational procedures.
- 2.4.2. The organisation shall facilitate the consultation of staff by providing the methods and means for involving staff, recording staff's opinion and providing feedback on staff's opinion.

3. PLANNING

3.1. Actions to address risks

3.1.1. Risk assessment

3.1.1.1. The organisation shall:

- (a) identify and analyse all operational (including human performance), organisational and technical risks relevant to the type, extent and area of operations carried out by the organisation. Operational risks shall include at least those arising from work activities, job design or fatigue and the activities of other interested parties (see 1.1. Organisation, context and scope of the safety management system);
- (b) evaluate the risks referred to in point (a) by applying appropriate risk assessment methods;
- (c) develop and put in place safety measures, with identification of associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
- (d) develop a system to monitor the effectiveness of safety measures (see 6.1. Monitoring);
- (e) recognise the need to collaborate with other interested parties (such as railway undertakings, infrastructure managers, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on shared risks and the putting in place of adequate safety measures;
- (f) communicate risks to staff and involved external parties (see 4.4. Information and communication).

- 3.1.1.2. When assessing risk, an organisation shall take into account the need to determine, provide and sustain a safe working environment which conforms to applicable legislation, in particular Council Directive 89/391/EEC.

3.1.2. Planning for change

- 3.1.2.1. The organisation shall identify potential safety risks and appropriate safety measures (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change) in accordance with the risk management process set out in the applicable Common Safety Method as referred to in Article 6(1)(a) of Directive (EU) 2016/798, including consideration of the safety risks from the change process itself.

3.2. Safety objectives and planning

- 3.2.1. The organisation shall establish safety objectives for relevant functions at relevant levels to maintain and, where reasonably practicable, improve its safety performance.

- 3.2.2. The safety objectives shall:
- (a) Be consistent with the safety policy and the organisation's strategic objectives (where applicable);
 - (b) Be linked to the priority risks that influence the safety performance of the organisation;
 - (c) Be measurable;
 - (d) Take into account applicable legal and other requirements;
 - (e) Be reviewed as regards their achievements and revised as appropriate;
 - (f) Be communicated.
- 3.2.3. The organisation shall have plan(s) to describe how it will achieve its safety objectives.
- 3.2.4. The organisation shall describe the strategy and plan(s) used to monitor the achievement of the safety objectives (see 6.1. Monitoring).

4. SUPPORT

4.1. Resources

- 4.1.1. The organisation shall provide the resources, including competent staff and effective and useable equipment, needed for the establishment, implementation, maintenance and continual improvement of the safety management system to ensure the safe operation and maintenance of its railway operations.

4.2. Competence

- 4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:

- (a) identification of the competencies (including knowledge, skills, non-technical behaviours and attitudes) required for safety-related tasks;
 - (b) selection principles (basic educational level, psychological and physical fitness required);
 - (c) initial training, experience and qualification;
 - (d) ongoing training and periodic update of existing competencies;
 - (e) periodic checks of competence, psychological and physical fitness, where appropriate.
- (f) specific training in relevant parts of the safety management system for staff at all levels within the organisation.
- 4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:
- (a) the training programme is delivered according to the identified competency requirements and individual needs of the staff;
 - (b) where applicable, the training ensures that staff can operate under all operating conditions (normal, degraded and emergency);
 - (c) the duration of the training and the frequency of the refresher training are appropriate for the training objectives;

- (d) records are kept for all staff (see 4.5.3. Control of documented information);
 - (e) the training programme is regularly reviewed and audited (see 6.2. Internal auditing) and changes made when necessary (see 5.4. Management of change).
- 4.2.3. Back to work arrangements shall be in place for staff following accidents/incidents or long absences from work, including providing additional training where such a need is identified.
- 4.3. Awareness
- 4.3.1. Top management shall ensure that they and their staff having a role that affects safety are aware of the relevance, importance and consequences of their activities and how they contribute to the correct application and the effectiveness of the safety management system, including the achievement of safety objectives (see 3.2. Safety objectives and planning).
- 4.4. Information and communication
- 4.4.1. The organisation shall define adequate communication channels to ensure that safety-related information is exchanged among the different levels of the organisation and with external interested parties including contractors, partners and suppliers.
- 4.4.2. To ensure that safety-related information reaches those making judgements and decisions, the organisation shall manage the identification, receipt, processing, generation and dissemination of safety-related information.
- 4.4.3. The organisation shall ensure that safety-related information is:
- (a) relevant, complete and understandable for the intended users;
 - (b) valid;
 - (c) accurate;
 - (d) consistent;
 - (e) controlled (see 4.5.3. Control of documented information);
 - (f) communicated before it takes effect;
 - (g) received and understood.
- 4.5. Documented information
- 4.5.1. Safety management system documentation
- 4.5.1.1. There is a description of the safety management system including:
- (a) the identification and description of the processes and activities related to safety of rail operations, including safety-related tasks and associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
 - (b) the interaction of these processes;
 - (c) the procedures or other documents describing how these processes are implemented;
 - (d) the identification of contractors, partners and suppliers with a description of the type and extent of services delivered;
 - (e) the identification of contractual arrangements and other business agreements, concluded between the organisation and other parties identified under (d),

necessary to control the safety risks of the organisation and those related to the use of contractors;

(f) reference to documented information required by this Regulation.

4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:

- (a) a synthesis of the decisions on the level of significance of the safety-related changes, including an overview of significant changes, in accordance with Article 18(1) of the applicable Common Safety Method as referred to in Article 6(1)(a) of Directive (EU) 2016/798;
- (b) the organisation's safety objectives for the following year(s) and how serious risks for safety influence the setting of these safety objectives;
- (c) the results of internal accident/incident investigation (see Learning from accidents and incidents) and other monitoring activities (see 6.1. Monitoring, 6.2. Internal auditing and 6.3. Management review), in accordance with Article 5(1) of the applicable Common Safety Method for monitoring as referred to in Article 6(1)(c) of Directive (EU) 2016/798;
- (d) details of progress on addressing outstanding recommendations from the national investigation bodies (see 7.1. Learning from accidents and incidents);
- (e) the organisation's safety indicators set out to evaluate the organisation's safety performance (see 6.1. Monitoring);
- (f) where applicable, the conclusions of the annual report of the safety advisor on the activities of the organisation relating to the transport of dangerous goods.

4.5.2. Creating and updating

4.5.2.1. The organisation must ensure that when creating and updating documented information related to the safety management system an adequate format and media are used.

4.5.3. Control of documented information

4.5.3.1. The organisation must control documented information related to the safety management system, in particular its storage, distribution and the control of changes, to ensure its availability, suitability and protection where appropriate.

5. OPERATION

5.1. Operational planning and control

5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:

- (a) risk acceptance criteria and safety measures are applied (see 3.1.1. Risk assessment);
- (b) plan(s) to achieve the safety objectives are delivered (see 3.2. Safety objectives and planning);
- (c) information is collected to measure the correct application and effectiveness of the operational arrangements (see 6.1. Monitoring).

5.1.2. The organisation shall ensure that its operational arrangements conform to the safety-related requirements of applicable Technical Specifications for Interoperability and

relevant national rules (see 1.1. Organisation, context and scope of the safety management system).

- 5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:
 - (a) planning of existing or new train routes and new train services, including the introduction of new types of vehicles, the need to lease vehicles and/or to hire staff from external parties and the exchange of information on the maintenance for operational purposes with entities in charge of maintenance;
 - (b) development and implementation of train timetables;
 - (c) preparation of trains or vehicles before movement, including pre-departure checks and train composition;
 - (d) running trains or movement of vehicles in the different operating conditions (normal, degraded and emergency);
 - (e) adaptation of the operation to requests for removal from operation and notification of return to operation issued by entities in charge of maintenance;
 - (f) authorisations for movements of vehicles.
- 5.1.4. To control the allocation of responsibilities where relevant for the safety of operational activities, the organisation shall identify responsibilities for coordinating and managing the safe running of trains and movements of vehicles and define how relevant tasks affecting the safe delivery of all services are allocated to competent staff within the organisation (see 2.3. Organisational roles, responsibilities, accountabilities and authorities) and to other external qualified parties when appropriate (see 5.3. Contractors, partners and suppliers).
- 5.1.5. To control information and communication where relevant for the safety of operational activities (see 4.4. Information and communication), relevant staff (e.g. train crews) shall be advised of the details of any specified conditions of travel, including relevant changes which may result in a hazard, temporary or permanent operational restrictions (e.g. due to specific type of vehicles or to specific routes) and conditions for exceptional consignments, where these are required.
- 5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1.1. Organisation, context and scope of the safety management system), for its staff:
 - (a) compliance with their training and work instructions, and corrective actions are taken where required;
 - (b) specific training in case of anticipated changes affecting the running of operations or their task assignment;
 - (c) adoption of adequate measures following accidents and incidents.
- 5.2. Asset management
 - 5.2.1. The organisation shall manage the safety risks associated with physical assets throughout their lifecycle (see 3.1.1. Risk assessment), from design to disposal, and fulfil the human factors requirements for use.
 - 5.2.2. The organisation shall:

- (a) ensure that the assets are used for the purpose intended while maintaining their safe operational state, in accordance with Article 14(2) of Directive (EU) 2016/798 where relevant, and their expected level of performance;
 - (b) manage the assets in normal and degraded operations;
 - (c) detect as soon as reasonably practicable instances of non-compliance with operating requirements before or during the operation of the asset, including the application of restrictions of use as appropriate to ensure a safe operational state of the asset (see 6.1. Monitoring).
- 5.2.3. The organisation shall ensure that its asset management arrangements, where applicable, conform to all essential requirements as set out in the relevant Technical Specifications for Interoperability (see 1.1. Organisation, context and scope of the safety management system).
- 5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:
- (a) the identification of the need for maintenance to keep the asset in a safe operational state, based on the planned and real use of the asset and its design characteristics;
 - (b) the management of the removal of the asset from operation for maintenance, when defects have been identified or when asset condition degrades outside the limits of a safe operational state as referred to in point (a);
 - (c) the management of the return to operation of the asset with eventual restrictions of use after maintenance has been delivered to ensure it is in a safe operational state;
 - (d) the management of calibrated or verified monitoring and measurement equipment.
- 5.2.5. To control information and communication where relevant for the safety of asset management (see 4.4. Information and communication), the organisation shall take into account:
- (a) the exchange of relevant information within the organisation or with external entities responsible for maintenance (See 5.3. Contractors, partners and suppliers), in particular on safety-related malfunctions, accidents, incidents as well as on eventual restrictions of use of the asset;
 - (b) the traceability of all necessary information including the information related to point (a) (see 4.4. Information and communication and 4.5.3. Control of documented information);
 - (c) the establishment and maintenance of records of all assets including the management of the configuration of all changes affecting the safe integrity of the assets (see 5.4. Management of change).
- 5.3. Contractors, partners and suppliers
- 5.3.1. The organisation shall identify and control safety risks arising from outsourced activities, including operations or cooperation with contractors, partners and suppliers.
- 5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation must define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:
- (a) the competence requirements (see 4.2. Competence);
 - (b) the responsibilities for the tasks performed;

- (c) the achievement of the expected results and safety performance;
 - (d) the obligations relating to the exchange of safety-related information (see 4.4. Information and communication);
 - (e) the traceability of safety-related documents (see 4.5. Documented information).
- 5.3.3. In accordance with the process set out in the applicable Common Safety Method for monitoring as referred to in Article 6(1)(c) of Directive (EU) 2016/798, the organisation must monitor:
- (a) the safety performance and results of all activities and operations of contractors, partners and suppliers to ensure that they comply with the requirements set out in the contract;
 - (b) the awareness of contractors, partners and suppliers of safety risks they entail to the organisation's operations.
- 5.4. Management of change
- 5.4.1. The organisation shall implement and control changes to the safety management system to maintain or improve the safety performance, including the decision points that shall determine the continuation on this course and the review of potential changes to the safety risks (See 3.1.1. Risk Assessment).
- 5.4.2. The organisation shall notify the relevant authority about any substantial change in accordance with Article 10 of Directive (EU) 2016/798 and identify the need to apply for a new authorisation for placing on the market of a vehicle or for an update of the single safety certificate when required.
- 5.5. Emergency management
- 5.5.1. There are procedures in place to identify the emergency situations and associated measures to be taken to manage them (see 3.1.1. Risk assessment) and to re-establish normal operating conditions in accordance with the applicable Technical Specification for Interoperability relating to the operation and traffic management subsystem.
- 5.5.2. There are procedures in place to ensure that, for each identified type of emergency:
- (a) the emergency services can be promptly contacted;
 - (b) the emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency;
 - (c) first aid is provided internally.
- 5.5.3. The roles and responsibilities of all parties are identified and documented in accordance with the applicable Technical Specification for Interoperability relating to the operation and traffic management subsystem.
- 5.5.4. Plans for action, alerts and information in case of emergency exist and include arrangements to:
- (a) alert all staff with responsibility for emergency management;
 - (b) communicate information to all parties (e.g. infrastructure manager, contractors, authorities, emergency services), including emergency instructions for passengers;
 - (c) take any decisions required in accordance with the type of emergency.
- 5.5.5. The organisation shall describe how resources and means for emergency management have been allocated (see 4.1. Resources) and how training requirements have been identified (see 4.2. Competence).

- 5.5.6. The emergency arrangements are regularly tested in cooperation with other interested parties and updated when appropriate.
- 5.5.7. The organisation shall ensure that competent staff in charge, with adequate language skills, can be contacted easily and without delay by the infrastructure manager and provide the latter with the right level of information.
- 5.5.8. There is a procedure to contact the entity in charge of maintenance or the railway vehicle keeper in the event of an emergency.
- 5.5.9. Following a serious accident, the railway undertaking shall provide guidance to victims helping them in complaints procedures under Union legislation, in particular Regulation (EC) No. 1371/2007 on rail passengers' rights and obligations¹⁶, without prejudice to the obligations of other parties. Such assistance shall use channels for communicating with victims' families and include psychological support for accident victims and their families.

6. PERFORMANCE EVALUATION

6.1. Monitoring

- 6.1.1. The organisation shall perform monitoring in accordance with the applicable Common Safety Method for monitoring as referred to in Article 6(1)(c) of Directive (EU) 2016/798:
 - (a) to check the correct application and the effectiveness of all the processes and procedures in the safety management system, including the operational, organisational and technical safety measures;
 - (b) to check the correct application of the safety management system as a whole, and if it achieves the expected outcomes;
 - (c) to investigate whether the safety management system conforms to the requirements in this Regulation;
 - (d) to identify, implement and evaluate the effectiveness of the corrective measures (see 7.2. Continual improvement), as appropriate, if any relevant instance of non-compliance to points (a), (b) and (c) is detected.
- 6.1.2. The organisation shall regularly monitor at all levels within the organisation the performance of safety-related tasks and intervene if these tasks are not being properly performed.

6.2. Internal auditing

- 6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:
 - (a) A schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance;
 - (b) The identification and selection of competent auditors (see 4.2. Competence);
 - (c) The analysis and evaluation of the results of the audits;
 - (d) The identification of the need for corrective or improvement measures;
 - (e) The verification of the completion and effectiveness of these measures;

¹⁶ OJ L 315, 3.12.2007, p. 14.

- (f) The documentation pertaining to the execution and results of audits;
- (g) The communication of the results of audits to the top management.

6.3. Management review

- 6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:
 - (a) details of progress on addressing outstanding actions from previous management reviews;
 - (b) changing internal and external circumstances (see 1.1. Organisation, context and scope of the safety management system);
 - (c) the organisation's safety performance related to:
 - (i.) the achievement of its safety objectives;
 - (ii.) the results from its monitoring activities, including the internal audit findings, and internal accident/incident investigations and status of their respective actions;
 - (iii.) the relevant outputs from supervisory activities conducted by the national safety authority;
 - (d) recommendations for improvement.
- 6.3.2. Based on the outputs of its management review, the top management shall take overall responsibility for the planning and implementation of needed changes to the safety management system.

7. IMPROVEMENT

7.1. Learning from accidents and incidents

7.1.1. Accidents and incidents related to the organisation's railway operations shall be:

- (a) reported, logged, investigated and analysed to determine their causes;
- (b) reported to national bodies as appropriate.

7.1.2. The organisation shall ensure that:

- (a) recommendations from the national safety authority, the national investigating body and industry/ internal investigations are evaluated and implemented if appropriate or mandated;
- (b) relevant reports/information from other interested parties such as railway undertakings, infrastructure managers, entities in charge of maintenance and railway vehicle keepers are considered and taken into account.

7.1.3. The organisation shall use information relating to the investigation to review the risk analysis and evaluation (see 3.1.1. Risk assessment), to learn and, where required, to adopt corrective measures (see 5.4. Management of change).

7.2. Continual improvement

7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in the applicable Common Safety Method for monitoring as referred to in Article 6(1)(c) of Directive (EU) 2016/798 and at least the outputs of the following activities:

- (a) Monitoring (see 6.1. Monitoring);

- (b) Internal auditing (see 6.2. Internal auditing);
 - (c) Management review (see 6.3. Management review);
 - (d) Learning from accidents and incidents (see 7.1. Learning from accidents and incidents).
- 7.2.2. The organisation shall provide means to motivating staff and other interested parties to be active in improving safety as part of its organisational learning.

DRAFT



SINGLE SAFETY CERTIFICATE

Single Safety Certificates confirming acceptance of the railway undertaking's safety management system including the provisions adopted by the railway undertaking to meet specific requirements necessary for safe operation on the relevant network in conformity with Directive (EU) 2016/798 and applicable national legislation

EU IDENTIFICATION NUMBER: _____

1. CERTIFIED RAILWAY UNDERTAKING

Legal denomination:	
Railway undertaking name:	Acronym:
National registration number:	VAT No:

2. AUTHORITY ISSUING CERTIFICATE

Organisation:
Country:

3. CERTIFICATE INFORMATION

This is a <ul style="list-style-type: none"> - new certificate <input type="checkbox"/> - renewed certificate <input type="checkbox"/> - updated certificate <input type="checkbox"/> 	EU Identification Number of the previous certificate: _____								
Validity from: _____ to: _____									
Type of operation ¹⁷ : <table style="width: 100%; border: none;"> <tr> <td style="text-align: center; vertical-align: middle;">Passenger transport</td> <td style="padding: 0 10px;">including services</td> <td style="padding: 0 10px;">high-speed</td> <td style="text-align: right;"><input type="checkbox"/></td> </tr> <tr> <td></td> <td style="padding: 0 10px;">excluding services</td> <td style="padding: 0 10px;">high-speed</td> <td style="text-align: right;"><input type="checkbox"/></td> </tr> </table>		Passenger transport	including services	high-speed	<input type="checkbox"/>		excluding services	high-speed	<input type="checkbox"/>
Passenger transport	including services	high-speed	<input type="checkbox"/>						
	excluding services	high-speed	<input type="checkbox"/>						

¹⁷ For each Member State concerned by the intended area of operation.

	including dangerous goods services	<input type="checkbox"/>
Freight transport		
	excluding dangerous goods services	<input type="checkbox"/>
Shunting only		<input type="checkbox"/>
Other operations ¹⁸ :		

4. APPLICABLE NATIONAL LEGISLATION¹⁹

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5. AREA OF OPERATION AND EXCLUSIONS²⁰

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6. LIMITATIONS AND CONDITIONS OF USE

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7. ADDITIONAL INFORMATION

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Date issued _____

¹⁸ For each Member State concerned by the intended area of operation.

¹⁹ For each Member State concerned by the intended area of operation.

²⁰ Exclusions of part(s) of the network in accordance with Article 10(7) of Directive (EU) 2016/798.

²¹ For each Member State concerned by the intended area of operation.

Internal reference number

Signature and/or
stamp

DRAFT